Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 176-201, 204-223, 226-241, 243-265 and 268-282 are pending in the application, with claims 176, 210, 232, 249, 250, 251, 253, 254, 255, 263, 274, 275, 276, 277, 278, 279 and 280 being the independent claims. Claims 202-203, 224-225, 242 and 266-267 are canceled. Claims 176, 178-182, 188, 190-194, 206, 210, 212-216, 228, 232, 241, 245, 249-251, 253-255, 263, 270 and 274-282 are sought to be amended. No new matter is added by way of these amendments. It is respectfully requested that the amendments be entered and considered.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

Support for the amendment of claims 176, 178-182, 188, 190-194, 210, 212-216, 232, 241, 249-251, 253-255, 263 and 274-282 can be found throughout the specification, for example, at page 4, lines 4-12; page 7, lines 17-23; page 15, line 19 to page 16, line 3; page 18, line 29 to page 19, line 8; page 23, lines 14-16; page 25, lines 3-6; page 34, lines 25-28; Table 1; Examples 1-8; and in the claims as originally filed. Support for the amendment of claims 206, 228, 245 and 270 can be found throughout the specification, for example, at page 4, lines 4-12; page 23, lines 27-30; and in the claims as originally filed.

I. Finality of Present Office Action

According to the Office Action Summary and the United States Patent and Trademark Office's Patent Application Information Retrieval (PAIR), the Office Action dated November 2, 2005 is non-final. However, in the Conclusion section the Examiner states that "THIS ACTION IS MADE FINAL." (Office Action, page 8.) Applicants' undersigned representative contacted the Examiner by telephone on May 2, 2006, and pointed out this discrepancy. In this telephone conversation, the Examiner confirmed that the outstanding Office Action was non-final, and that the statement in the Office Action indicating that the Action is Final was in error. Accordingly, this Amendment and Reply is being filed under 37 C.F.R. § 1.111.

II. Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 176-180, 182-192, 194, 214, 216-282 were rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement for compositions comprising serum-free media and embryonic stem cells from animals other than mice. (Office Action, pages 2-3.) Applicants respectfully traverse this rejection.

As amended herein, independent claims 176, 210, 232, 249-251, 253-255, 263 and 274-280 are directed to compositions, methods and products of manufacture comprising "mouse or primate" embryonic stem cells. On page 2 of the Office Action, the Examiner states that the specification is enabling "for a composition of mouse embryonic stem cells and serum-free media."

Further, declarations under 37 C.F.R. § 1.132 by Paul Price and Mary Tilkins were filed and received by the Patent Office on November 12, 2002. In these declarations, it is stated that the Invitrogen product KNOCKOUT SR™ is one embodiment of the present invention and that KNOCKOUT SR™ has been used successfully to culture embryonic stem cells of mouse, human and primate origin. In the subsequent Office Action dated November 10, 2003, at pages 4-6, the Examiner withdrew the 35 U.S.C. § 112, first paragraph, rejection. Whether a claim is enabled under 35 U.S.C § 112 is determined in view of the *Wands* factors. (*See, e.g.*, Manual of Patent Examining Procedure (MPEP), Eighth Edition, August 2001, Latest Revision October 2005 § 2164.01.) The court in *Wands* stated that "[e]nablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue' experimentation." (*In re Wands*, 858 F.2d 731, 736-737.) The Examiner concluded:

> [g]iven these facts as supported by the efforts of the skilled artisans in the art, Examiner would agree that having the methods and materials known and used for culturing mouse and human embryonic stem cells as a starting reference point, that methods for culturing other stem cells will be obtained, in particular providing a precisely defined media absent of the variables of serum recognized as the greatest variable in successfully culturing embryonic stem cells.

(Office Action dated November 10, 2003, page 6.) Applicants' assert that the present specification enables the culturing of embryonic cells from other species in addition to mouse and primate embryonic cells. However, solely to advance prosecution, Applicants have amended the claims herein to refer to mouse and primate embryonic cells.

In view of these amendments and remarks Applicants assert that the claims directed to "mouse and primate" embryonic stem cells are fully enabled under 35 U.S.C. § 112 and respectfully request reconsideration and withdrawal of this ground of rejection.

III. Claim Rejections Under 35 U.S.C. § 103

Claims 176-182 were rejected under 35 U.S.C. § 103(a) as being obvious over Ponting (U.S. Patent No. 5,405,772), GIBCO BRL Products and Reference Guide ((1997) Chapters 5 and 8; referred to hereafter as the "GIBCO reference") and Atsumi *et al.* (Develop. Growth & Differ. 35(1):81-87 (1993)). (Office Action, page 6.) Applicants respectfully traverse this rejection.

Applicants submit that to establish a *prima facie* case of obviousness, the Examiner must meet at least three criteria. First, the Examiner must show that the references upon which she of he relied teach every limitation of the currently claimed invention. (*In re Royka*, 490 F.2d 981, 985 (Fed. Cir. 1974).) Second, the Examiner must show that there is some suggestion or motivation in the references themselves, or within the knowledge of one of ordinary skill in the art, to combine the references to arrive at the claimed invention. (*See, e.g.*, MPEP § 2143.01.) Lastly, the Examiner must show that there is a reasonable expectation of success in combining the references, and that this expectation of success is found in the references as well. (*In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).)

A. Not All Elements Of The Claims Are Taught By The Cited References

The claims as amended herein relate to a cell culture medium or serum-free supplement that is "capable of preventing differentiation of the mouse or primate embryonic

stem cells during expansion of the embryonic stem cells". Ponting, the GIBCO reference or Atsumi *et al.* do not teach or suggest a culture medium that prevents differentiation of embryonic stem cells.[1] Since not all elements of the currently presented claims are taught or suggested by the cited references, a *prima facie* case of obviousness cannot be established.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 103(a).

B. No Motivation to Combine

The Federal Circuit held in *Northern Telecom, Inc. v. Datapoint Corp.* (908 F.2d 931, 934, (Fed. Cir. 1990)) that "[i]t is insufficient that the prior art disclosed the components of the patented device, either separately or used in other combinations; there must be some teaching, suggestion, or incentive to make the combination made by the inventor."

The Examiner states:

> [w]hile Ponting does not specifically disclose all the specific components listed in the claims, the use of these components would be obvious because they are factors commonly used in cell culture.

(Office Action, page 7.) Following the Examiner's reasoning, any combination of known cell culture factors would be obvious for growing any particular known cell-type.

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[1] Additionally, Applicants refer the Examiner to the related remarks set forth in Applicants responses dated November 17, 2004, pages 27-28 and dated August 18, 2005, pages 5-7.

Additionally, none of the cited references teach or suggest a culture medium or supplement that prevents cell differentiation and comprises a lipid-rich albumin. The GIBCO reference does list, as potential growth supplements, AlbuMAXI® and AlbuMAXII®, which are lipid-rich albumin products. However, none of the references cited in this rejection suggest the use of cell culture medium comprising lipid-rich albumin products for culturing embryonic stem cells and/or for preventing differentiation of embryonic stem cells. Therefore, there was no motivation or suggestion to arrive at the subject matter of Applicants' claimed invention. Therefore, a *prima facie* case of obviousness has not been established.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 103(a).

C. No Reasonable Expectation of Success

None of the references suggest that cell culture medium comprising a lipid-rich albumin can be successfully used during the expansion of embryonic stem cells and will prevent differentiation of embryonic stem cells, which is the subject matter of the presently claimed invention. As discussed above, none of the references teach or suggest a culture medium that prevents cell differentiation and comprises a lipid-rich serum albumin. As a result, the references do not, as required, provide a reasonable expectation of success as related to the subject matter of the claimed invention. Thus, a *prima facie* case of obviousness cannot be established based on the cite references.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 103(a).

D. The Rejection May Be Based on an Improper "Obvious to Try" Standard

As noted above, the Examiner states:

> [w]hile Ponting does not specifically disclose all the specific components listed in the claims, the use of these components would be obvious because they are factors commonly used in cell culture.

(Office Action, page 7.) Applicants believe the Examiner may be applying an incorrect "obvious to try" standard for the obviousness rejection.

The Federal Circuit has consistently held that "obvious to try" is not to be equated with obviousness under 35 U.S.C. § 103. (*See, e.g., In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir 1988).) The end result of a pursuit is not obvious simply because it may be obvious to try to achieve such a result. In the instant case, the end result of a culture medium that prevents embryonic cell differentiation and comprises a lipid-rich serum albumin is not obvious simply because lipid-rich serum albumin may have been previously used in cell culture and that preventing embryonic cell differentiation is a desired function. Therefore, Applicants respectfully submit that the rejection has been based on an improper "obvious to try" standard.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 103(a).

Conclusion

It is not believed that extensions of time are required beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefore are hereby authorized to be charged to the Deposit Account No. 19-0036.

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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